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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,888	08/20/2001	Michael E. Spurlock	PM-8935-A	7993

54704 7590 04/04/2006

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,888	SPURLOCK ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-20,22-28,30,42-62 and 64-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-20,22-28,30,42-62 and 64-87* is/are rejected.

7)☒ Claim(s) *17, 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 13, 17-20, 22-28, 30, 50, 52, 57, 62, 64, 66-68, 70-72, 74-76, 78-83 have been amended and 84-87 have been added as requested in the paper filed 24 August 2005. Claims 1-12, 21, 29, 31-41, 63 have been canceled. Claims 13-20, 22-28, 30, 42-62, 64-87 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 24 August 2005 have been fully considered but they are not deemed to be persuasive.

37 C.F.R. § 1.3

> 37 C.F.R. 1.3 " Business to be conducted with decorum and courtesy. Applicants and their attorneys or agents are required to conduct their business with the United States Patent and Trademark Office with decorum and courtesy. Papers presented in violation of this requirement will be submitted to the Director and will not be entered. A notice of the non-entry of the paper will be provided. Complaints against examiners and other employees must be made in correspondence separate from other papers."

Applicant is reminded of proper conduct before the PTO. Attention is directed to pages 25 (first full paragraph, line 1), 26 (last paragraph, line 5), 35 (last paragraph),

and 36 (top of page). Applicant is advised that future papers presented in violation of 37 CFR 1.3 will be submitted to the Director and will not be entered.

Cancelled claims

Applicant's statements regarding allowability of cancelled claims is noted. However, Applicant has no basis to argue this point since the claims are no longer pending in the application.

> Applicant's continued assertion after every argument that the claims are allowable is noted. However, the Examiner will hold conclusions regarding patentability till the end of the Office action.

Claim Objections

Claims 17-18 stand objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for the reasons of record in the previous Office action(s). Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims depend from base claims which have two requirements: 1) the DNA molecule must encode a porcine adipocyte leptin and 2) must hybridize to a specified sequence. The dependent claims 17-18 place size limitations on the DNA of "at least 20" or "at least 50" bases, which is no where near the necessary size of a DNA which will encode a porcine leptin polypeptide, absent evidence to the contrary. Therefore, the claims do not appear to further limit the claims from which they depend.

Claims 17 and 18 appear to be broader than the claim from which it depends. Claim 13 is directed to a DNA molecule that encodes a porcine leptin, wherein the DNA hybridizes to a specified molecule with a specified sequence. Claim 17 appears to encompass any fragment ("at least about 20 bases and encodes at least a fragment") and claim 18 appears to encompass any fragment ("at least about 50 bases and encodes at least a fragment"). This language encompasses many more types of molecules than does claim 13, based on the fragment language, and therefore, is broader in nature. Because it is broader, it does not further limit the base claim. It is additionally noted that stringent hybridization conditions for different length nucleic acid molecules varies, therefore, it is not clear if the conditions listed in claim 13 would be the same or different from those in claims 17 and 18, which also makes the claims indefinite.

Applicant argues the objection of claims 46-48, 51, 54, 59, 69, 73 and 77 by stating that the objection was not understood. To be clear, the object was made over the previously filed claims because of the interchangeable use of "porcine adipocyte polypeptide leptin" or "porcine leptin polypeptide" or "porcine leptin polypeptide leptin". Applicant's comments regarding "variants" is unclear to the Examiner because this term was never mentioned in the objection to these claims. The Objection is withdrawn in light of Applicant's amendment.

It is suggested that in future correspondence that Applicant address the rejections in the order in which they are presented. This would provide a prosecution history that is easier to follow and understand.

Claim Rejections - 35 USC § 112

Claims 19-30 and 41-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment which replaces SEQ ID NO:3 with SEQ ID NO:2 has obviated the rejection of claims 19-20, 22-28, 30, 46-52, 57, 62 and 64-83 for referring to "a nucleotide sequence of SEQ ID NO:3" (or depend from claims which recite SEQ ID NO:3).

Claims 13, 19-22, 24-25, 27-28, 62, 68, 81 were rejected for reciting the article "a" in place of "the" when referring to the sequence represented by a sequence identifier. This is indefinite when referring to a single sequence because reference to a specific sequence would require the use of the article "the". The use of "a" implies that there are multiple sequences to chose from or represented by the sequence identifier, which is not the case when referring to a specific sequence as one is when referencing a sequence identifier. Applicant asserts that the claims were definite in scope – this is a spurious argument with no reasoning to support it. Applicant refers to MPEP § 2173.05(e) as the rationale for using "a" or "an" in place of "the". After reading this section of the MPEP, the Examiner can find no mention or suggestion for using the article "a" or "an" in place of "the". The Examiner's explanation appears to be on point. Applicant's amendment to the claims has obviated this ground of rejection.

New claims 84 and 85 recite the limitation "the porcine leptin polypeptide". There is insufficient antecedent basis for this limitation in the claim. The article "the" implies that there is a single porcine leptin polypeptide to which the claim is referring, but no such protein is referenced. The use of the article "a" in place of "the" would obviate this ground of rejection.

Claims 14, 15, 17, 18, 19, 20, 44, 52, 55, 57, 60, 62, 64, 66, 70, 74, 78, 80, 82 are indefinite for the recitation "at least about" in conjunction with a number of nucleotides which are to hybridize. This recitation is indefinite because the lower limits of what are to be encompassed by the claims are not clear. The instant specification does not indicate what range "at least about" is meant to encompass. Furthermore, "at least" is in direct conflict with "about" since "at least" sets a lower limit to the range, but "about" changes that limit. Therefore, the claims are indefinite because the metes and bounds of "at least about" cannot be determined.

Applicant asserts that the term "at leas about X" could alternatively be written as "about X or more" and "no one of ordinary skill in the art would be confused about the meaning of "at least about X". Applicant's argument has been fully considered but is not found to be persuasive. The phrase "at least" has a definite meaning; it sets a very definite lower limit for the number of nucleotides which are to hybridize. The term "about" is not specific to the precise number of nucleotides which are to hybridize. The use of the two phrases/terms together makes the claims indefinite because the metes and bounds of the number of nucleotides which are to hybridize cannot be determined.

For example, does the claim encompass 15 nucleotides? Would 25 nucleotides be encompassed by "at least about 50"? Does the claim encompass 10 nucleotides? The skilled artisan would have no idea if they were infringing the claim because the metes and bounds are not clear and definite. The rejection is maintained for the reasons of record.

Claims 13-20, 22-28, 30, 42-62, 64-87 are indefinite for the limitation of "stringent hybridization conditions". The limitation "stringent hybridization conditions" is equivalent to reciting a range without indicating the metes and bounds of the conditions since there is no indication of what conditions are to be encompassed by the claims. The specification does not provide a definition of what conditions are considered "stringent" and the art recognizes a multitude of conditions which could be used and considered "stringent". Because a multitude of conditions are encompassed by the claims, it is not clear which molecules which may hybridize under varying conditions are encompassed by the claims. Therefore, the metes and bounds of the claims are unclear and the claims are indefinite.

Applicant argues this rejection at pages 27-30. Applicant's arguments have been considered, but are not deemed to be persuasive. Applicant states that the use of broad terminology does not necessarily render a claim indefinite. Applicant is correct in saying that breadth does not equate to indefiniteness. However, this is not the case in the instant application. The metes and bounds of the claims cannot be determined because the claims encompass a wide host of molecules depending on which conditions are intended by the terminology "stringent hybridization conditions" and those

skilled in the art would not know which conditions are intended by the claims because the metes and bounds of what is covered by the claims is unclear. In the absence of a true definition in the specification that indicates what conditions are intended by "stringent", the rejection is maintained for the reasons of record.

Claims 16, 23-24, 26-28, 45, 56, 61, 67, 71, 75, 79, 83 and new claims 84-85 are directed to nucleic acid molecules (DNA, mRNA) which "hybridizes" to "substantially all" of the bases of a recited sequence. However, these claims are indefinite for the failure to indicate what is intended by the recitation "substantially all".

Applicant argues at pages 30-32 that "substantially all" is definite. Applicant's arguments have been carefully considered but have not been found to be persuasive. First, Applicant again refers to U.S. Pat. No. 6,756,484. Again, the Examiner will not comment on the prosecution of another application. This patent is not directed to nucleic acid molecules which hybridize to substantially all of the bases of a recited sequence. Therefore, it is not germane to the instant fact situation. Applicant's assertion of "differential treatment" is not supported by any facts of record.

The specification does not define "substantially all" and its use in conjunction with the indefinite "stringent hybridization conditions" clearly does not provide sufficient explanation of the metes and bounds of the claims. Applicant states that "the meaning of the term "substantially all" clearly means something less than "all," yet more than "half". Applicant has provided no basis in the specification for this conclusion or definition. Applicant may mean 50%-100%, but someone in the art may view

"substantially all" to be 80-100% while another researcher may view this to be 90-100%. Because the metes and bounds of what is being claimed is unclear, the claims are indefinite.

Claims 13-15, 17-20, 25, 30, 41-42, 44, 50, 52, 53, 55, 57,58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first step in determining if a claim meets the enablement requirements of 35 U.S.C. 112, first paragraph, is understanding what is being claimed. The instant claims are directed to nucleic acid molecules which encode a porcine leptin polypeptide, wherein the nucleic acid hybridizes to at least about 20-50 bases of SEQ ID NO:1, 20-50 bases of SEQ ID NO:3, or wherein the nucleic acid molecule is at least 20-50 bases long. It is clear that the instant specification encompasses and intends for fragments of porcine leptin to be encompassed in the scope of the invention. However, the instant specification only describes a single protein which can be called "porcine adipocyte polypeptide leptin" or "porcine leptin polypeptide" or "porcine leptin polypeptide leptin" , and this protein is 166 amino acids in length with the signal sequence and 145 amino acids in length without the signal sequence. The prior art nucleic acid molecules which encode leptin are also described in Figure 4, which encode a leptin of a similar length to

that of the disclosed porcine leptin. The specification distinguishes fragments from the "leptin" depicted in Figure 2 at page 7 of the specification; "[a]lso intended within the scope of the present invention is any polypeptide having at least about 8 amino acids present in the above-mentioned sequence." Therefore, the claims are directed to nucleic acid molecules which encode porcine leptin (functional limitation) wherein the nucleic acid molecule hybridizes to at least about 20 (or 50) nucleotides of a disclosed nucleic acid molecule or wherein the isolated nucleic acid molecule is at least about 20 (or 50) bases in length (structural limitation).

First, the art does not recognize a nucleic acid as short as 20-50 nucleotides long that encodes a leptin molecule and the instant specification fails to teach a molecule meeting this limitation. The specification does teach that a fragment of 20 nucleotides is intended in the scope of the claims, but it does not teach that this length is sufficient for encoding leptin as defined in the instant specification as corresponding to SEQ ID NO:2. Therefore, one of ordinary skill in the art would not find such a length sufficient for encoding a leptin molecule from pigs, absent evidence to the contrary, and the claims are not enabled for such. Next, SEQ ID NO:1 is a genomic sequence with significantly long stretches of non-coding regions. The claims encompass isolated DNA which hybridizes to at least 20 or 50 nucleotides of SEQ ID NO:1, however, the vast majority of the nucleic acid molecules which hybridize (again, no conditions are provided, so the majority of nucleic acids in existence would hybridize under various conditions) to 20 or 50 bases would not meet the functional requirements of the claims, which are to encode

a porcine leptin polypeptide. The structure which is given is not sufficient to result in the required function of the claims, and the claims are not enabled.

Applicant argues the rejection at pages 25-30 of the response. However, Applicant's arguments are based on the premise that a nucleic acid molecule of "at least about" 20 bases encodes porcine leptin. For the reasons given above and supported by the disclosure of the instant specification, this is a false premise. Therefore, the rejection is maintained for the reasons of record and for those reasons given above. Applicant may wish to amend the claims to eliminate the functional requirement that the isolated nucleic acid molecule encode porcine leptin, and this may obviate this ground of rejection.

Claim Rejections - 35 USC § 103

Claims 22-28 and 42-62, 64-83 and newly filed claims 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (U.S. Pat. No. 6,309,853) for the reasons of record in the previous Office actions.

The instant specification defines a functional derivative as

> Any "fragment", "variant", "analog", or "chemical derivative" of the porcine adipocyte polypeptide that retains at least a portion of the function of the porcine adipocyte polypeptide which permits its utility in accordance with the present invention. (page 9 of the specification)

The instant claims are directed to isolated nucleic acids which encode porcine leptin or a "functional derivative thereof" or "variant thereof" . The prior art of Friedman et al. (U.S. Pat. No. 6,309,853) disclose nucleic acids which encode human and mouse

leptin, which would be considered functional derivatives and/or variants of the disclosed porcine leptin since they encode leptin molecules and would possess similar functional properties as those of the porcine leptin, absent evidence to the contrary. Friedman et al. teach that the leptin gene (or OB) could be isolated from domestic animals using the methods disclosed therein (see column 26, line 53 to column 27, line 49). Friedman et al. specifically mention swine as a domestic animal for which leptin would be useful (see column 48, lines 41-57). Friedman et al. do not specifically disclose an isolated nucleic acid encoding a porcine leptin polypeptide. However, it would have been obvious to use the nucleic acid of Friedman et al. encoding human or mouse leptin and hybridize it to a porcine cDNA library and isolate a nucleic acid molecule encoding porcine leptin because Friedman et al. teach methods for isolating leptin encoding nucleic acids and also teach that it would be beneficial to administer leptin to swine. It would also have been prima facie obvious to use the nucleic acid of Friedman et al. encoding human or mouse leptin and hybridize it to porcine genomic DNA to isolate the gene encoding porcine leptin because it would have been beneficial to more completely understand the gene structure of porcine leptin. It also would have been prima facie obvious to use the nucleic acid of Friedman et al. encoding human or mouse leptin and hybridize it to porcine mRNA to isolate the mRNA encoding porcine leptin for the benefit of understanding the nature of porcine leptin expression. Therefore, the invention as a whole would have been obvious at the time it was made, absent evidence to the contrary.

Applicant argues the rejection at pages 34-36 of the response. Applicant's arguments appear to be based on the premise that the porcine leptin of the instant application is functionally different from the human and mouse leptin of the prior art. However, the rejection is not one of anticipation, but rather that the human and mouse leptin of the prior art meet the limitation of being functional derivatives based on the disclosure of the instant specification at page 9. A ""functional derivative" refers to any "fragment", "variant", "analog", or "chemical derivative" of the porcine adipocyte polypeptide that retains at least a portion of the function of the porcine adipocyte leptin" (see page 9 at lines 4-5). Therefore, Friedman et al. teach nucleic acid molecules which are "functional derivatives" and "derivatives" of the porcine leptin of the instant application and because they possess "at least a portion of the function of the porcine adipocyte leptin". Friedman et al. teach that the nucleic acid molecules encoding leptin could be used to isolate nucleic acid molecules encoding leptin from other species, specifically swine, contrary to Applicant's assertion that "the Friedman patent does not teach, suggest or disclose the invention of the above-identified application". The claims are broadly directed to isolated nucleic acids which encode porcine leptin – based on the known high degree of nucleic acid similarity of the leptin molecules across species (taught in Friedman), the known existence of a porcine leptin molecule (taught in Friedman), motivation to isolate nucleic acid molecules encoding porcine leptin (taught in Friedman) and known methods of isolation of nucleic acid molecules encoding leptin using one species as a probe (taught in Friedman), the invention as a whole would have been *prima facie* obvious in view of Friedman.

Applicant's arguments at pages 34-35 regarding specific activities of porcine leptin are noted, but do not avoid the rejection of record. The claims do not require these specific activities and the specification only requires "at least a portion of the function of the porcine adipocyte leptin". This function would include any function, such as binding to a leptin receptor, antigenicity, etc. Therefore, Applicant's arguments are not persuasive.

Applicant argues that "the Examiner switched horses and basically alleged Applicants could only consider functional properties disclosed for porcine leptin in the present application. This is an erroneous and overly restrictive view by the examiner." Applicant's arguments have been considered, but are not persuasive. The claims do not require the isolated molecule to encode a porcine leptin with any particular biological activity. If one of ordinary skill in the art used the polynucleotides of Friedman et al. to hybridize to porcine polynucleotides using the methods taught in Friedman et al., there is more than a reasonable expectation of success in isolating a porcine version of leptin, absent evidence to the contrary.

Applicant argues at the bottom of page 35- page 36 that the Examiner merely makes conclusions and does not properly reject the claims under 103. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only

from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, the rejection was based on the disclosure of Friedman, the success Friedman had in isolating a different species of leptin while using another species as a probe, the disclosure that leptin existed in pigs, and the specific statement of motivation in Friedman to isolate the molecules from other species, including pigs. Applicant has not provided any evidence on the record that one of ordinary skill in the art could not follow the teachings and guidance in Friedman et al. to isolate nucleic acids encoding leptin in pigs. The fact that the encoded protein has some very specific biological properties in the pig is interesting, but not persuasive for the reasons given above and does not avoid the rejection of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud